National Cancer Institute Division of Cancer Epidemiology and Genetics Chornobyl Oversight Panel Meeting Summary

Meeting Date:

July 17, 2000

Members Present:

Patricia Hartge, Robert Hoover, Charles Land, Elaine Ron, Shelia

Zahm (Chair)

Others Present:

Gilbert Beebe, Andre Bouville, Alina Brenner, Barry Fountos, Nick

Luckyanov, Ihor Masnyk, Sharon Miller, Jacob Robbins, Kathleen

Stine, Terry Thomas, Bruce Wachholz,

Next Meeting:

September 5, 2000 - 10:30 a.m.-12:30 p.m. - EPS Conference

Room 7107

I. Review of Meeting Summaries and Action Items from Past COP Meetings

The summaries and action items from the May 1st meeting were accepted without correction.

II. Thyroid Cancer Study

A. Re-Screening

The Re-Screening Subcommittee met in May and developed proposals that were discussed in the June meetings overseas. Another meeting of the subcommittee is planned for July 27-28. Dr. Thomas summarized the plans and reported on the proposed changes to the operations manual and forms. Ukraine and Belarus have been asked to send suggestions on the form changes. The proposal is for study subjects to be screened every two years, although Belarus plans annual screening for subjects under age 18. A meeting of the clinicians from each country is planned for September in Minsk to develop standardized criteria for fine needle aspirations and follow-up.

B. Funds for Belarus

Dr. Masnyk reported that the subcontract for local support in Belarus has left the Fogarty International Center on June 27, 2000 for the State Department. When the State Department approval is received the money will be sent to Belarus the next day. Approval for future support through the ISTC was resubmitted. Approvals by the State Department and the Moscow sector of ISTC are needed. The ISTC cannot be used to provide the incentives for the study subjects. Dr. Masnyk is trying to arrange for payment through the International Red Cross.

III. June Meetings in Ukraine and Belarus

A. Administration

Dr. Masnyk reported that the official order to establish a new screening center in Gomel was signed. Funds have been transferred to Columbia University for equipment purchases to start the center. A bus has been purchased and delivered to Minsk to aid in recruitment and screening efforts. It is likely that another bus will be needed for the Gomel center. Decisions need to be made concerning the division of oblasts, whether to do all laboratory work in Minsk or to establish a second laboratory in Gomel. Dr. Fink has developed a proposal to eliminate the laboratory backlog by the fourth quarter of 2000.

In Ukraine, over 9,000 subjects have been screened. The response rate has increased due to the \$5 incentive and due to giving one individual responsibility for each raion. Dr. Romenenko will be retiring his ministerial position, but will retain his position as Project Director.

B. Dosimetry

Dr. Bouville described the third joint meeting of dosimetrists from Belarus, Ukraine, Russia, and the U.S. for the thyroid studies, that was held in Minsk. Efforts to establish the methodology to estimate radiation doses continue. A similar model will be applied in all countries, as far as similarities in the data permit. Dr. Luckyanov will be developing the programming for the model and send it to our collaborators for review in August or September. The model should be operational by November.

Efforts to develop and use personal interview data for dosimetry were also discussed at the meeting in Minsk. The general format of a joint questionnaire was approved at the meeting. Dr. Thomas and Brenner are finalizing the questionnaire, script, and instructions. A report on testing of the reliability of the variables will be prepared for the November meeting. Because of poor reliability of responses from subjects who were young children at the time of the accident, interviews for subjects' parents are also being considered.

An alternative method to estimate dose is based on environmental measures of ¹³¹-I taken in the contaminated areas in the weeks after the accident. The plans were to use this method only in Belarus, but researchers in Ukraine want to apply the method in their study as well. Subcontracts to the persons developing the estimates will be issued. Members of the Chornobyl Oversight Panel discussed whether CDC might be persuaded to support these activities with money from the fall-out project. Alternatively, Tor Strom of the University of Utah may be able to do this work under the existing Columbia subcontract with the University of Utah. Dr. Bouville and Dr. Masnyk will contact Columbia to see if Dr. Strom might be able to provide this service before the subcontract expires in September.

The dosimetry work for the leukemia study involves efforts to improve the EPR method, incorporation of environmental data, and evaluation of the missing official dose records. The French agency, IPSN, has decided against heavy involvement in Phase II of the leukemia study.

Dr. Fountos reported on problems with the dosimetry data in the DOE study on cataracts among liquidators, some of whom are also subjects in the NCI study of leukemia. The findings of DOE's planned external review of dosimetry data will be highly relevant for the NCI study.

C. Epidemiology

In June, plenary meetings were held in each country to present an overview of the thyroid studies, then small meetings were held in each country with epidemiologists and data coordinating center staff. A joint meeting of epidemiologists from both countries was held, but only one person attended from Belarus due to a problem with the invitations. The meeting was successful, however, and a decision was made to continue to have joint epidemiology meetings on a regular basis.

The meeting focused on the new quarterly reporting format. The Ukrainian team tried to fill out the form prior to the meeting, which was very useful for identifying problems. A revised format was developed. After a few more changes, Dr. Thomas will distribute the new format to the Panel and use of the new form will be implemented. The new format will yield better information on response rates. A narrative report and dosimetry table will continue to be required for each quarterly report.

Additional work is needed on the databases. For example, each record needs to indicate the round of screening. A trip to Belarus is needed to review the documentation and revise data in the files before the second round of screening starts. In Ukraine, the University of Illinois has developed twelve volumes in both languages in three months documenting each data collection form, variables names, coding instructions, keying instructions, edit checks, and data cleaning programs. The Chornobyl Research Unit will carefully review the material, particularly the data cleaning programs, and indicate changes as needed. The Panel discussed possible ways to involve the University of Illinois in the Belarus operations. Dr. Thomas will review the results of a pilot study in Ukraine to determine the optimal procedures for double-keying data.

Various options of publishing the study background, purpose, methods, and statistical power have been discussed by Dr. Thomas, Dr. Beebe, Dr. Howe, and the collaborators in Ukraine and Belarus. The collaborators want separate papers from Ukraine and Belarus, but may agree to some joint publications as well.

Phase I of the leukemia project piloted the study methods in one oblast. Dr. Thomas and

Dr. Howe plan to visit Ukraine to visit each of the six oblasts participating in the full-scale study. Currently, every two oblasts are overseen by one person. It may be necessary to improve the supervision in each oblast. Also, the current plan is for hematologists to abstract data in each oblast. Dr. Thomas and Dr. Howe will investigate if there are more economical methods of abstracting the data than using these highly qualified (and presumably higher paid) persons.

IV. Meeting of International Groups Conducting Chornobyl-Related Research

Dr. Thomas has polled international groups conducting Chornobyl-related research and found that a meeting of the group cannot be held in November. The International Agency for Research on Cancer has offered to host the meeting, but it was decided that it would be better to hold the meeting in the Washington, D.C. area to allow greater participation by NCI staff. Next April, which coincides with the 15th anniversary of the Chornobyl accident, was proposed for the date of the meeting.

V. Report on Columbia Contract Funds

Ms. Miller reported that the projected \$1.5 million contract overrun has been reduced to approximately \$900,000 through negotiations with Columbia University and changes in the contract effort, the indirect cost adjustments, and correction of errors. The overrun is due to increased costs related to NCI-directed changes in payment for travel costs, purchase of special supplies and equipment. Next year is a contract option year. Careful evaluation of the personnel needed on the contract should result in further economies. A discussion was held of ways to utilize the remainder of the University of Utah subcontract, which expires September 29, 2000.

VI. Chornobyl Tissue Repository

Dr. Wachholz reported that the tissue repository would be operational in a few months. An announcement of its availability and applications for its use will be made in September.

VII. ACERER Review

The draft recommendations of the ACERER Subcommittee were reviewed. The full ACERER Committee will finalize the report and recommendations on a conference call on August 4, 2000. Members of the Chornobyl Research Unit will prepare draft responses to the ACERER recommendations for the next meeting of the Chornobyl Oversight Panel.

VIII. Tri-National Thyroid Study Collaborators Meeting, November, 2000

The Tri-National Thyroid Study Collaborators Meeting is planned for November 13-15. Dr. Robbins is organizing a workshop to be held on November 16 to consider whether to continue to include urinary iodine measurement in the screening protocol. Outside experts will be invited to

participate. The Re-screening Subcommittee will have a meeting on November 17 to finalize the operational manual and forms for the rescreening protocol.

Future COP Meetings, 10:30-12:30, EPS/7107:

July 27-28, Thyroid Re-Screening Meeting Sept. 5

Oct. 2

Nov. 6, if needed

Nov. 13-15, Tri-National Thyroid Study

Collaborators Meeting

Nov. 16, Urinary Iodine Workshop

Nov. 17, Thyroid Re-Screening Meeting

Dec. 11